IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)
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Atsuo F. Fukunaga, et al.	) Examiner: Joseph F. Weiss
	)
Serial No. 09/930,821	) Atty. Docket: 10413-31
	)
Filing Date: August 15, 2001	)
	)
Entitled: UNILIMB RESPIRATORY CONDUIT, PROXIMAL TERMINAL AND PROXIMAL FITTING	)

Assistant Commissioner For Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR §1.132
OF KEVIN D. BURROW

Sir:

I, Kevin D. Burrow, hereby declare the following:

1. I have reviewed the patent application referenced above to Dr. Atsuo Fukunaga and his co-inventor, and understand the inventions for which patent protection is sought. I have also reviewed the cited patent, U.S. Patent 5,284,160 to Dryden, which is licensed to King Systems Corporation ("King"). The recited invention is not taught or suggested by the prior art, including the cited Dryden patent.
2. I am Vice President of King, and have been so since 1979.
3. King produces breathing circuits, filters therefore, and related equipment for assisted ventilation and anesthesia systems ("the field"), and has done so since 1977.
4. At King, I have become familiar with many devices in the field and their methods of construction. I helped develop and patent improvements in the field. For example, I am a co-inventor of an anesthesia circuit claimed in U.S. Patent 5,404,873.
5. In 1989, I became familiar with and negotiated a license on behalf of a King to Dr. Atsuo Fukunaga's U.S. Patent 4,265,235. King's efforts to produce the

device covered thereby resulted in the commercial product known as the Universal F® (hereinafter Universal F).

6. I assisted King in acquiring rights to the cited U.S. Patent 5,284,160, to Dryden, before we knew of and acquired rights to the presently claimed invention, which we refer to as the Universal F2®. I am familiar with what Dryden teaches. It does not teach a multilumen proximal fitting as recited in the claims.

7. In the field, we have sought to produce devices at minimum cost, yet with maximum safety. We tried to produce the Universal F in the most economical manner possible while maintaining patient safety as our number one concern. Therefore, we made sure that the proximal end of the inspiratory gas line was firmly bonded to the proximal terminal.

8. The construction of the Universal F proximal terminal and circuit required expensive manufacturing steps designed to ensure that the proximal end of the flexible inspiratory gas tube did not become detached during use.

9. The Universal F, despite higher manufacturing costs, met with commercial success due to its many beneficial features. However, the entire circuit was designed to be disposed of after a single use due to the bonding of the respiratory conduits to the proximal terminal. The Universal F was not designed to have the two flexible respiratory conduits attachable to and detachable from the proximal terminal at the site of use. Had we known of a way to make the respiratory conduits safely attachable and detachable at the site of use, substantial cost and effort could have been avoided.

10. Until Dr. Fukunaga showed us the specification of the priority application of the present application, U.S. Patent Application 08/751,316 (the F2 application), we were unaware of any device that would permit attachment of a multilumen respiratory conduit by a user to a proximal terminal and detachment therefrom after use at the site of use. Further, it was a well-known policy in the field to bond the respiratory conduits to the proximal terminal. Simply hearing that such a device had been made was insufficient to convince us that it was feasible or safe. Only after studying the F2 application were we convinced that not only could we have a multilumen respiratory conduit that a user could attach to a multilumen

proximal terminal at a site of use and detach therefrom after use, but that such a device was safe.

11. A key feature of detachability was discovery of the new proximal fitting of the present invention, which made it possible to attach a multilumen conduit to the new multilumen proximal terminal. Prior to the present invention, I knew of no teaching or motivation to make a detachable multilumen respiratory conduit independent of a multilumen proximal terminal. Dryden simply enabled King to include a sampling tube into a Universal F device.

12. The Universal F2® proximal fitting and proximal terminal have led to considerable cost savings in manufacturing over the Universal F®. Further, the Universal F2® has met with commercial success, as customers only need to buy one proximal terminal for use with multiple conduits. Since we do not have to bond flexible respiratory conduits to the proximal terminal, manufacturing costs have substantially decreased. Further, the conduits are easy to manufacture, and take up less space in storage and in shipping than full circuits with proximal terminals attached.

13. Our commercial success is clearly attributable to the inventive features of the invention. Specifically, the Universal F invention peaked at no more 20% of our gross revenues, whereas the Universal F2® proximal fitting and proximal terminal have already reached more than 38% of our gross revenues in only about 5 years, despite little change in our marketing efforts. The technical features of the Universal F2® proximal fitting and proximal terminal are what has led to this great success as customers recognize considerable benefits for patients and a hospital's bottom line.

14. The Dryden patent does not teach how to make a circuit with a multilumen respiratory conduit that is attachable to and detachable from a multilumen proximal terminal at the site of use. Otherwise, we at King would have made such a device years ago. The swivel of Dryden is not designed to be constructed and deconstructed at the site of use. Further, applicable industry standards would be violated by trying to use Dryden as a proximal fitting. ISO 5356-1 and industry guidelines call for device and tubing connectors in respiratory circuits to have

smooth tapered fittings. Dryden's bent flanges would interfere with a sealed fit, and it would not be practical to attempt to create and destroy the swivel of Dryden at a site of use.

15. One of ordinary skill in the art would find Dryden's Figure 1 not to be operative, and would also interpret it as requiring attachment at its proximal end to flexible tubing. For example, the flanges on the device in Figure 1 of Dryden are specifically taught for connection to flexible tubes, and this only way we at King, the exclusive Licensee, interpreted Dryden. Dryden does not teach how the tubes or the device in Figure 1 could be connected to an anesthesia machine, and hence is not operative and/or an enabling teaching of a useful device.

16. The uniqueness of the present inventions of a multilumen proximal fitting and the corresponding multilumen proximal terminal is evident in the surprise of our customers. While the cost of replacing just the multilumen respiratory conduit is much less than replacement of the proximal terminal bonded to the multilumen conduit, the unobviousness of the present invention is evident from the need to convince customers that they can save money and be safe.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Kevin D. Burrow — 4/30/03

Kevin D. Burrow — Date